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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/080,942      | 02/22/2002  | Fred Zulli           | 1761-0013           | 6515             |

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[REDACTED] EXAMINER

DAVIS, RUTH A

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1651     | 9            |

DATE MAILED: 04/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |
|------------------------------|------------------------|---------------------|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |
|                              | 10/080,942             | ZULLI ET AL.        |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |
|                              | Ruth A. Davis          | 1651                |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 10 January 2003 and 26 March 2003.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,2 and 5-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 1,2 and 5-9 is/are allowed.
- 6) Claim(s) 10-14 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

|  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s) _____   |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>6</u> | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

Applicant's amendments filed January 10 and March 26, 2003 have been received and entered into the case. Claims 3 and 4 have been cancelled; claims 8 – 14 have been added. Claims 1 – 2 and 5 – 14 are pending and have been considered on the merits. All arguments have been fully considered.

### ***Claim Objections***

Claim 12 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Claim Rejections - 35 USC § 102***

Rejections under 35 U.S.C. 102 have been withdrawn due to amendment.

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 10 and 13 – 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nippon Oils, Hwang or Peters.

Applicant claims a cosmetic composition comprising at least one biologically active isoflavone aglycone selected from genistein and daidzein; which is incorporated into liposomes in a concentration of 1 – 500 mg/kg, or alternatively 20 – 100 mg/kg. The liposomes have a diameter of 100 – 140 nm.

Nippon Oils teaches a composition of isoflavones, specifically genistein, incorporated into liposomes (abstract).

Hwang teaches compositions comprising genistein incorporated into liposomes (col.7 line 39-48).

Peters teaches compositions of isoflavones incorporated into liposomes for cosmetic use (col.1 line 17-26), specifically daidzein and genistein (col.2 line 1-2).

The above references do not teach the claimed concentration of isoflavones or diameters of liposomes in the compositions. However, at the time of the claimed invention, it was well

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within the purview of one of ordinary skill in the art to optimize effective amounts of active ingredients as well as sizes of liposomes as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the concentration of isoflavones in the composition of any one of the references, with a reasonable expectation for successfully obtaining a composition of isoflavones and liposomes.

4. Claims 10 and 13 – 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saruno or Gorbach in view of Lanzendorfer.

Applicant claims a cosmetic composition comprising at least one biologically active isoflavone aglycone selected from genistein and diadzein; which is incorporated into liposomes in a concentration of 1 – 500 mg/kg, or alternatively 20 – 100 mg/kg. The liposomes have a diameter of 100 – 140 nm.

Saruno teaches topical cosmetic compositions comprising genistein wherein the composition exhibits antimicrobial and antioxidant activity (abstract).

Gorbach teaches cosmetic compositions of genistein and/or diadzein for treating/preventing the signs of aging (abstract). The compositions are incorporated into transdermal delivery systems and may in forms of lotions, creams, oils, sprays and gels (col.1 line 60-67).

The references do not teach the compositions incorporated into a liposome. However, Lanzendorfer teaches that active components incorporated into liposomes improves penetration into the skin and achieve a sustained release and/or preserving effect (col.17 line 44-52). At the

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time of the claimed invention, one of ordinary skill in the art would have been motivated by Lanzendorfer to incorporate the active ingredients of Saruno or Gorbach into the liposome of Lanzendorfer because of the improved skin penetration action as disclosed by Lanzendorfer. One of ordinary skill in the art would have been further motivated to incorporate the ingredients of Gorbach into the liposome of Lanzendorfer because Gorbach specifically teaches the isoflavones compositions may be incorporated into transdermal delivery systems (of which liposomes are). Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Lanzendorfer to incorporate the active agents of either Saruno or Gorbach into a liposome with a reasonable expectation for successfully improving penetration of the compositions.

The above references do not teach the claimed concentration of isoflavones or diameters of liposomes in the compositions. However, at the time of the claimed invention, it was well within the purview of one of ordinary skill in the art to optimize effective amounts of active ingredients as well as sizes of liposomes as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the concentration of isoflavones in the composition of any one of the references, with a reasonable expectation for successfully obtaining a composition of isoflavones and liposomes.

5. Claims 10 – 11 and 13 – 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chikamatsu and Matsuda in view of Lanzendorfer.

Applicant claims a cosmetic composition comprising at least one biologically active isoflavone aglycone selected from genistein and diadzein; which is incorporated into liposomes in a concentration of 1 – 500 mg/kg, or alternatively 20 – 100 mg/kg. The liposomes have a diameter of 100 – 140 nm. The composition further includes at least one algal extract.

Chikamatsu teaches cosmetic compositions comprising isoflavones, specifically diadzein and genistein, for inhibiting melanin formation (or has a whitening effect) (abstract).

Matsuda teaches cosmetic compositions comprising extracts of blue-green algae that have a skin whitening effect (abstract).

The above references do not teach a composition comprising a combination of isoflavones and algae extract. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine the instant ingredients for their known benefit, as disclosed by the cited references above, since each is well known in the art for their whitening effect. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518.

The references do not teach the compositions wherein the active agents are incorporated into a liposome. However, Lanzendorfer teaches that active components incorporated into liposomes improves penetration into the skin and achieve a sustained release and/or preserving effect (col.17 line 44-52). At the time of the claimed invention, one of ordinary skill in the art would have been motivated by Lanzendorfer to incorporate the composition obtained by the combined references into the liposome of Lanzendorfer because of the improved skin penetration action as disclosed by Lanzendorfer. Moreover, at the time of the claimed invention, one of

ordinary skill in the art would have been motivated by Lanzendorfer to incorporate the active agents of Chikamatsu and Matsuda into a liposome with a reasonable expectation for successfully improving penetration of the compositions.

The above references do not teach the claimed concentration of isoflavones or diameters of liposomes in the compositions. However, at the time of the claimed invention, it was well within the purview of one of ordinary skill in the art to optimize effective amounts of active ingredients as well as sizes of liposomes as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the concentration of isoflavones in the composition of any one of the references, with a reasonable expectation for successfully obtaining a composition of isoflavones and liposomes.

6. Claims 10 – 11 and 13 – 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saruno and Kikuchi in view of Lanzendorfer.

Applicant claims a cosmetic composition comprising at least one biologically active isoflavone aglycone selected from genistein and diadzein; which is incorporated into liposomes in a concentration of 1 – 500 mg/kg, or alternatively 20 – 100 mg/kg. The liposomes have a diameter of 100 - 140 nm. The composition further includes at least one algal extract.

Saruno teaches cosmetic compositions comprising genistein wherein the composition exhibits antimicrobial and antioxidant activity (abstract).

Kikuchi teaches cosmetic compositions comprising algae extracts wherein the composition exhibits antioxidant activity (abstract).

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The above references do not teach a composition comprising a combination of isoflavones and algae extract. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine the instant ingredients for their known benefit, as disclosed by the cited references above, since each is well known in the art for their antioxidant activity. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518.

The references do not teach the compositions wherein the active agents are incorporated into a liposome. However, Lanzendorfer teaches that active components incorporated into liposomes improves penetration into the skin and achieve a sustained release and/or preserving effect (col.17 line 44-52). At the time of the claimed invention, one of ordinary skill in the art would have been motivated by Lanzendorfer to incorporate the composition obtained by the combined references into the liposome of Lanzendorfer because of the improved skin penetration action as disclosed by Lanzendorfer. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by Lanzendorfer to incorporate the active agents of Saruno and Kikuchi into a liposome with a reasonable expectation for successfully improving penetration of the compositions.

The above references do not teach the claimed concentration of isoflavones or diameters of liposomes in the compositions. However, at the time of the claimed invention, it was well within the purview of one of ordinary skill in the art to optimize effective amounts of active ingredients as well as sizes of liposomes as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by

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routine practice to optimize the concentration of isoflavones in the composition of any one of the references, with a reasonable expectation for successfully obtaining a composition of isoflavones and liposomes.

Applicant argues that the references do not recited concentrations of aglycones, are concerned with therapeutic compositions, not cosmetics, and that there is no motivation or suggestion to alter concentrations of aglycones. Applicant further argues that the composition has specific therapeutic effects not taught in the art.

However, these arguments fail to persuade because as stated above, at the time of the claimed invention, it was well within the purview of one of ordinary skill in the art to optimize such variables as a matter of routine experimentation. Further it is unclear if applicant intends the composition as a cosmetic as claimed and argued, or a pharmaceutical as also argued. It is noted that the claims are not directed to a therapeutic composition. It is reiterated that both aglycones and liposomes were routinely used in both cosmetics and therapeutic compositions as disclosed by the cited references. Therefore, at the time of the claimed invention, one of ordinary skill in the art would have been motivated to incorporate cosmetic and/or therapeutic compositions of aglycones into liposomes with a reasonable expectation of success.

***Allowable Subject Matter***

On March 26, 2003, claims 1 – 9 were indicated allowable subject matter to applicant's representative, Michael Beck. However an agreement to the claims was not met.

Claim 12 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 703-308-6310. The examiner can normally be reached on M-H (7:00-4:30); altn. F (7:00-3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-0196. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ruth A. Davis; rad  
March 27, 2003



LEON B. LANKFORD, JR.  
PRIMARY EXAMINER